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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/284,199	08/02/1994	MICHAEL M. BURRELL	1130261 CONT.	4511
7590	11/17/2003			
Samuel B. Abrams PENNIE & EDMONDS LLP 1155 Avenue of the Americas New York, NY 10036-2711			EXAMINER FOX, DAVID T	
			ART UNIT 1638	PAPER NUMBER 37
DATE MAILED: 11/17/2003				

Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary

Application No.

08/284,199

Applicant(s)

BURRELL ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003 and 20 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66-67 is/are allowed.
- 6) ☒ Claim(s) 68-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 07/628,216.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 34.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 14 August 2003 have overcome the indefiniteness rejection. Applicant's arguments of 14 August 2003 have overcome the scope of enablement rejection of claims 62, 77 and 95 regarding tubers.

Claims 68-96 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office action on pages 2-4.

Claims 68-96 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in the last Office action for claims 5-7.

The claims remain free of the prior art, as stated on page 7 of the last Office action.

Claims 60-67 are allowed.

Applicant's arguments filed 14 August 2003 and 20 August 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the disclosure in the instant specification of various enzymes and their E.C. numbers, as well as the isolation by other workers of the genes encoding them.

The Examiner maintains that the instant specification is completely silent with regard to any sequence of any *gene*, wherein said gene sequence (and the conservation of any particular sequence domains correlated with function) would be needed in order to demonstrate possession of the broadly claimed genus. See MPEP 2163 and the Written Description Guidelines cited previously. The situation is eminently analogous to *University of California v. Lilly* cited previously, where the disclosure of an encoded protein corresponding to a single enzyme was deemed insufficient to describe the gene encoding it, even when a gene sequence encoding the same enzyme from a different animal species was disclosed. Furthermore, the instant specification does not even provide a particular amino acid sequence for a particular enzyme, but rather merely lists general classes of enzymes from any source and of any sequence. In addition, the instant specification does not provide any gene sequence information, and only anecdotally demonstrates the isolation of a phosphofructokinase gene and plant transformation therewith. Thus, the instant specification provides even less information than that in the *University of California v. Lilly* case, wherein even the more substantial specification in that case was deemed inadequate to enable the claims. It is also noted that the claims at issue in the *Lilly* case were more narrowly drawn to a gene encoding a particular enzyme from a particular animal species source, while the instant claims do not specify any source of the gene or enzyme, and are drawn to multiple enzymes or a

class of enzymes. Again, if the specification in *Lilly* was insufficient to describe their more narrow claims, the less substantial specification in the instant application cannot describe even broader claims.

Regarding the publications submitted by Applicant, the Examiner maintains that the instant specification must provide an adequate written description, not prior or later art. It is noted that several of the references which actually teach *gene* sequences were published after the effective filing date of the instant application.

Applicant urges that the remaining enablement rejection is improper, given the ability of Applicant to obtain alterations in carbohydrate metabolism following plant transformation with other genes, as demonstrated by the Coates declaration appended to the amendment of 14 August 2003, as well as Burrell declarations filed previously. Applicant further urges that the von Schaewen et al reference cited by the Examiner does not support his position.

The Examiner notes that the Coates declaration and Burrell declarations rely upon antisense constructs or multiple sense constructs corresponding to the same gene, neither of which concept or constructs were taught in the instant specification. In addition, the Coates declaration and Burrell declarations rely upon particular genes which were not disclosed in the instant specification.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Furthermore, the first Burrell declaration relies upon a specification of a different application which was filed more than a year and a half after the effective filing date of the instant application, and which issued almost four years after the filing of the instant application. That application discloses a completely different gene and enzyme, as well as antisense constructs and techniques, neither of which were disclosed in the instant specification.

See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Regarding von Schaewen et al, the Examiner maintains that the reference indeed demonstrates the unpredictability inherent in plant transformation with non-exemplified carbohydrate metabolism genes. Applicant's assertions that the skilled artisan would know which signal sequences to employ or avoid are not probative, and Applicant's specification is completely silent with regard to the use or choice of any signal sequence.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 10, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.